UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

In re. PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE LITIGATION	MDL No. 1456 Civil Action No. 01-12257-PBS Hon. Patti Saris
THIS DOCUMENT RELATES TO UNITED STATES OF AMERICA, EX REL. VEN-A-CARE OF THE FLORIDA KEYS, INC. v. ABBOTT LABORATORIES, INC., AND HOSPIRA, INC.	

UNITED STATES' MEMORANDUM IN OPPOSITION TO DEFENDANTS' MOTIONS FOR A FINDING OF SPOLIATION AND FOR SANCTIONS

Abbott Laboratories, Inc., (Abbott) and Dey, Inc. (Dey) have asked the Court to find that the Government has failed to preserve evidence and that the material which has purportedly been spoliated is "critical" to this case. *See* Dkt. 6097 (Abbott motion), Dkt. 6110 (Dey motion).[1/] Neither assertion is true. Pursuant to long-standing retention policies and specific directives concerning this MDL, the Government agencies at issue here, the Centers for Medicare and Medicaid Services (CMS) and the Office of Inspector General of the Department of Health and Human Services (OIG) have preserved extensive material relating to the subject matter of this case. That material, amounting to hundreds of thousands of pages of documents and millions of lines of data, has been produced to defendants and other litigants in this MDL, beginning in 2004 – several years before the United States' intervention in these cases. Moreover, defendants'

[1/] On July 9, 2009, the Roxane defendants also filed a spoliation memorandum, to which the Government will respond by separate brief.

arguments regarding the legal relevancy of the material alleged to have been spoliated are meritless.

The principle contention stated by defendants with regard to allegedly spoliated evidence is that the material might somehow show that Government officials not only knew about AWP abuse, but affirmatively believed that the inflated payment amounts which resulted from that abuse were consistent with drug payment policies in place at both the federal and state levels. Defendants' relevancy arguments ignore two fundamental features of Government payment policy. First, these policies are developed and implemented on the public record. Second, the public record, which includes details about the Government's efforts over the years to understand the extent to which compendia AWP were reflective of prices at which drugs could be obtained, is extensive. Additionally, defendants premise their relevancy arguments on what they characterize as "core propositions" and "unassailable facts" which the Government has purportedly asserted or implied at some unspecified point in this case. In reality, these alleged "propositions" are simply straw men that have no place in the Government's case, as demonstrated by the record in this litigation. Indeed, both the Court and the Special Master appointed by the Magistrate Judge, relying on the Government's actual allegations, have found that the types of material which are precisely covered by the spoliation motions are not even subject to discovery.[2/]

Defendants also ignore the most salient feature of the government approval issue which is now the center point of their defense. Any purported approval of defendants' pricing practices by

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[2/] On July 24, 2009, the Government will file its dispositive briefs in these cases. Legal issues discussed below substantially overlap with points to be argued in the upcoming summary judgment memoranda. Accordingly, the Government suggests that consolidated consideration of these briefs may be appropriate or, alternatively, that consideration of the spoliation motions be deferred until after the Court has ruled on the dispositive briefs.

the Government is only pertinent in so far as it was directly communicated to defendants and actually impacted their scienter during the time frames they were reporting false prices. Thus, the relevant evidence on this subject can only come from defendants. Documents which defendants have never seen, whether or not they ever existed, cannot have affected their scienter during the claims periods in these cases. Defendants' contentions regarding the sufficiency of the payment data and claims information used by the Government's expert to develop damage estimates are appropriately considered via the separate *Daubert* motions that have already been filed in these cases.

Finally, defendants' briefs fail to provide a full and accurate account of the steps taken by the Government to preserve evidence, as well as its document productions in this case. The Government took reasonable and timely steps to preserve material, which it then produced in the form of hundreds of thousands of pages of documents and millions of lines of data. Furthermore, there is no credible evidence that spoliation occurred at the federal or state level and defendants' few specific allegations about purportedly spoliated documents are false. Ultimately, defendants' motions are more properly understood as an attempt to blame the Government for their inability to proffer non-existent evidence in support of their defenses to the False Claims Act's scienter element.

Courts have adopted a five-factor test in deciding whether to impose sanctions for the destruction of evidence. Once destruction is established, consideration turns to: (1) whether the adversary was prejudiced by the destruction; (2) whether the prejudice can be cured; (3) the practical importance of the evidence; (4) whether the destruction was in good or bad faith; and (5) the potential for abuse if the evidence is not excluded or the party is not otherwise sanctioned. *McGuire v. Acufex Microsurgical, Inc.*, 175 F.R.D. 149, 156 (D. Mass. 1997). "All relevant

cases – not to mention state cases – look to among other things, prejudice *vel non* inuring to the adversary." *Id. See also Sacramona v. Bridgestone/Firestone, Inc.,* 106 F.3d 444, 448 (1st Cir. 1997) (court-imposed sanction must be limited to "what is necessary to cure the prejudice"). As demonstrated below, no spoliation of any relevant evidence occurred here. On an even more fundamental level, defendants cannot demonstrate that the types of evidence as to which they allege spoliation would be of any practical importance or that its alleged loss resulted in any identifiable prejudice.

I. DEFENDANTS' SPOLIATION ALLEGATIONS CONCERN IRRELEVANT DOCUMENTS

As demonstrated below, defendants' spoliation arguments (A) concern categories of material that are not relevant to the claims and defenses in this case; (B) fail to establish the relevance of specific categories of purportedly spoliated evidence under *any* legal theory; or (C) relate to issues properly considered in the context of the currently pending *Daubert* motions.

A. Defendants' Spoliation Allegations Are Not Relevant to the Claims Actually Pled by the United States or the Defenses Thereto

This litigation, as it pertains to Abbott, concerns four pharmaceutical products[3/] (for the sake of simplicity, "drugs") and as it relates to Dey, three drugs.[4/] The United States' complaints assert that defendants reported false prices (the "reported prices") for their respective drugs to the private companies which publish the compendia of Average Wholesale Prices ("AWPs") for pharmaceutical products, in violation of the federal False Claims Act, 31 U.S.C. §§ 3729-3733 ("FCA"). The Government further alleges that the Medicare and Medicaid programs relied on

[3/] The Abbott case involves three types of water-based solutions and the antibiotic Vancomycin.

[4/] The Dey drugs are Albuterol, Ipratropium Bromide and Cromolyn Sulfate.

the compendia prices to set payment rates for claims submitted for those drugs, that the defendants actually sold the drugs at far lower prices, and that the companies used the Government-funded "mega-spreads" between the inflated reimbursement amounts and the true costs of the drugs to induce present and potential customers to buy their products.

According to defendants, however, the "core propositions" upon which these cases depend relate to what government officials "believed" about the accuracy of "AWPs reported in the Compendia." Dkt. 6097 at 5, 9. Defendants further speculate that although they "can never know the full extent or importance of what has been destroyed," it might have "been useless or the classic 'smoking gun'." *Id.* at 10. As demonstrated below, prior rulings by the Court and Special Master, as well as controlling legal principles, make clear that the opinions of individual government employees about the accuracy of compendia AWPs or any other topic in defendants' briefs are not relevant to this case.

1. Prior Legal Rulings Relating to Government Knowledge

Since the very outset of this litigation, defendants have asserted that what the Government knew about AWP pricing is critical and that information known to government personnel may have been lost due to the age of the case. The Court explored this issue with defense counsel during a November 2007 oral argument on Abbott's motion to dismiss the Complaint of the United States. At that hearing, the Court was explicit that Abbott had failed to show that the evidence which had purportedly been lost "would have made a difference." 11/5/07 Trans. at 45:20 (Ex. A). The Court was also persistent in asking defense counsel what the documents could have shown: "What would you have found? I mean, that's why I wasn't persuaded. What would you have found if [the Government] had kept everything?" *Id.* at 46:4-

9. In response to defense counsel's assertion that purportedly missing documents would have shown general government knowledge of AWP spreads, the Court made a simple point: "But we know that up the kazoo. The government knew." *Id.* at 46:12-13.

Much earlier in the both the AWP and Lupron MDLs, defendant drug companies tried to make hay with the Government's AWP knowledge in the context of preemption and political question arguments. Both arguments were rejected in succession, first by the Court in this MDL and then by Judge Stearns in the Lupron MDL. Judge Stearns explicitly rejected the idea that the Government's knowing use of inflated prices to determine payment amounts established federal policy for the purposes of preemption.[5] Both he and Judge Saris were dismissive of the idea that government knowledge of inflated AWPs provided support for defendants' political question arguments.[6] When Abbott moved to dismiss the Complaint at the outset of the Government's FCA case, it attempted to resurrect the government knowledge issue by arguing that the Government's "undisputed" knowledge "that AWP was not an actual acquisition cost," gave rise to an estoppel defense. Abbott's motion to dismiss, in its entirety, was denied by the Court. *In re Pharmaceutical Industry Wholesale Price Litig.,* 491 F. Supp. 2d 12 (D. Mass. 2007).

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[5] Judge Stearns wrote that he was "not impressed with the argument that the failure of Congress to act more forcefully in making changes to what in some respects appears to be a flawed AWP reimbursement mechanism evidences any preemptive intent on its part," and quoted this Court's conclusion that "the fact that Congress has failed to disturb the widespread practice on the part of pharmaceutical companies of grossly overstating their AWPs cannot be read as a clear and manifest intention to grant immunity from state regulation of such fraudulent practices." *In re Lupron Marketing and Sales Practices Litig.,* 295 F. Supp. 2d 148, 178 (D. Mass. 2003) (quoting *Pharmaceutical Average Wholesale Price Litig.,* 263 F. Supp. 2d 172, 187-188 (D. Mass. 2003)).

[6] According to Judge Sterns, the "suggestion that Congress would deliberately condone a bribery scheme using public funds to enrich drug manufacturers and physicians is, to say the least, unusual." *In re Lupron Marketing and Sales Practices Litig.,* 295 F. Supp. 2d at 163. Judge Saris came to the same conclusion about the political question argument raised in the AWP MDL. *See Pharmaceutical Average Wholesale Price Litig.,* 263 F. Supp.2d at 181.

Nevertheless, defendants still cannot explain with any specificity how any category or item of evidence noted in the spoliation briefs is relevant, much less "critical" to their defense of the FCA claims pled by the United States. Instead, defendants assert that the Government has spoliated unspecified evidence that would somehow refute what Abbott has characterized as the "core propositions" underlying the Government's case, yet provide no explanation as to how these "propositions" are pertinent to any cause of action or defense. *See* Dkt. 6097 at 5. Markedly absent from Abbott's spoliation memorandum is citation to any government brief that asserts any of the "propositions" described by defendant. Where defendants have predicated the relevancy arguments in their spoliation motions on wholly fictitious "core propositions," they have failed to make even a *prima facie* case for sanctions given that spoliation can only apply to *relevant* evidence.

For example, according to Abbott, the United States has treated the following "proposition" as an "unassailable fact:" that "any payment above actual acquisition costs . . . or a small percentage margin (0% to 20%) . . . on these inexpensive drugs constitutes an 'overpayment' and 'false claim'..." *Id*. Abbott's description of the Government's position with respect to spreads in the lower end of the spread range is nothing short of pure fiction in light of the record in this case. In response to a specific inquiry from the Court, prompted by a previous mis-characterization by Abbott,[7] the Government explained that Abbott's contention that the Government was seeking a recovery based on the full extent of defendants' spreads was demonstrably *wrong* and that the first 25 percent of defendants' spreads had plainly been

[7] Abbott stated a similar mis-characterization when it sought permission to file an interlocutory appeal relating to the Court's rulings on the deliberative process privilege. At that time, Abbott asserted that, "[a]t bottom, the United States seeks in this case to recover *the full extent of* the 'spread,' or 'margin,' between the Medicare and Medicaid payments it made for four families of Abbott generic drugs..." Dkt. 5256 at 1 (emphasis supplied).

excluded from the damage estimates. *See* Dkt. 5551 at 6-7; Dkt. 5492 at 2. Moreover, the United States has sued defendants only for mega-spreads, with many of the sued-upon spreads exceeding 1000 percent - a significant, yet obvious, feature of this case which the Court has acknowledged. *See* Order at Dkt. 5665 at 2, 5.

In a similar vein, Abbott's assertion that the case brought by the Government is "dependent" on the "core principle" that "federal and state officials 'believed' AWPs reported in the compendia reflected or approximated prices in the marketplace" (Dkt. 6097, at 5), is refuted by every government brief filed in response to Abbott's repeated motions to compel. *See, e.g.,* Dkts. 4869, 4920, 5103, 5847. The Government has consistently argued that the views of individuals are completely irrelevant in light of (a) First Circuit precedent holding that issues of regulatory interpretation are resolved by reference only to the official public record (*United States v. Lachman*, 387 F.3d 42, 54 (1st Cir. 2004)), (b) the Court's discussion of regulatory intent behind the term AWP, which is entirely consistent with the *Lachman* analysis, and conclusion that the term would be construed as a matter of law (*In Re Average Wholesale Price Litig.,* 460 F. Supp. 2d 277, 278 (D. Mass. 2006)), and (c) the fact that the knowledge *of defendants*, not government officials, is relevant to the FCA's scienter element.

The "core propositions" and "unassailable facts" posited by Abbott are not only completely at odds with both the case pled by the United States, but also with the Court's understanding of the case as expressed in orders resolving previous discovery motions filed by defendants.

2. Defendants Allege Spoliation of Material Which Both the Court and Special Master Have Deemed Non- Discoverable

In ruling on Abbott's various discovery motions, the Court has found that only a limited class of material in the Government's files was even discoverable. For example, with respect to documents from CMS's Office of Legislation and Rulemaking Support Files, the Court directed only that the Government review the files from these sources "for documents relating to *Abbott's marketing the spread or the drugs at issue in this litigation*." Docket Entry Order of Mar. 12, 2008. During subsequent hearings in these cases, the Court marginally expanded the scope of the material that the Government should either produce or submit *in camera* to include documents which relate to mega-spreads for "inhalants" and "infusion drugs," the antibiotic Vancomycin, or the issue of "cross-subsidization.[8/]

Defendants' relevancy arguments as applied to particular types of documents are also at odds with the recent rulings by the Special Master. Significantly, the documents which the Government submitted *in camera* to the Special Master were not limited to just the types noted in the prior section of this brief - *i.e.* those which reference defendants' drugs, mega-spreads for inhalants or infusion drugs, cross-subsidization, etc. – but also documents designated by defendants based on their review of Government privilege logs, without regard to whether they fell within the narrower discoverability parameters stated by the Court. According to defendants, the documents before the Special Master constitute "crucial evidence." *See* Dkt. 5810-2 at 1. Moreover, defendants asserted that, through the appointment of a Special Master, the Court

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[8/] The Court addressed the scope of the Government's review of material from the Office of Legislation and Rulemaking Support Files at two hearings, one on July 24, 2008, the second on November 13, 2008. Copies of the hearing transcripts can be found at Dkt. 5847, Exhibits 1 and 2. Pertinent transcript sections are: Ex. 1 at 20:10-11, 23:19-24:14, Ex. 2 at 26:15-29, 27:7-8.

would "provide reasonable assurance that all evidence necessary for a full and fair resolution of these cases has been produced, and most of all, avoid the possibility of reversible error." Dkt. 5676 at 3.

On June 22, 2009, after an "individualized review" of all the documents submitted to him, the Special Master ruled for the Government as to every document except one, a memorandum, a draft version of which had been erroneously produced during a subpoena production by the United States before it became a party in the MDL. Many of the other documents before the Special Master were precisely the same type as those which defendants allege have been spoliated. For example, the defendants allege the Government failed to preserve the minutes of entrance and exit conferences between OIG and CMS relating to draft OIG reports. Dkt. 6097 at 17-18. Leaving aside that no spoliation of this material actually occurred, the Special Master did not order the Government to produce a single memorandum out of the dozens submitted *in camera* in this category. Rather, he found that:

> These are the kinds of documents regularly recognized as being protected by the deliberative process doctrine. They are predecisional and deliberative. The bulk of OIG workpapers has been released. The particular documents seem of limited relevance to the issues in the underlying case and the balance between the public interest in the protection of the deliberative process and the Defendants' particularized need for the information in this case falls clearly on the side of the Government.

Mem. and Order on *In Camera* Review of Documents, at 5, 8-9 (Ex. B). The Special Master reached much the same conclusion with respect to the other categories of *in camera* documents. *Id* at 5-16. In sum, the very types of documents alleged by defendants to be "critical" and to have been spoliated, were found by the Special Master to be irrelevant or, at best, of limited relevance but privileged.

3. Documents Which Defendants Have Never Seen Cannot Have Affected Their Scienter

Documents in the files of CMS or OIG which defendants have never seen, irrespective of whether they were preserved, are irrelevant to the determination of whether defendants "knowingly" reported false prices to the AWP compendia. As noted by this Court, the weight of authority holds that government approval regarding a false claim or statement does not shield a defendant from liability, and may be relevant only to whether a defendant made a "knowing misrepresentation." *See Massachusetts v. Mylan Laboratories,* 608 F. Supp. 2d 127, 149 (D. Mass. 2008) (quoting *United States v. Newport News Shipbuilding Inc.*, 276 F. Supp. 2d 539, 564 (E.D. Va. 2003)); *see also* Order at Dkt. 5665 at 12. The Court previously deferred on whether it would ultimately consider government approval as relevant only to a defendant's scienter or, alternatively, also to the underlying falsity of a claim or statement. *See* Dkt. 5665 at 15-16.

At this juncture, the Government believes that the majority rule on this issue should be followed. The only evidence that can have any relevance to defendants' scienter is that which comes from defendants' files. To be relevant, that evidence must show that defendants made full disclosure to the Government of all pertinent facts regarding their pricing of drugs in this case, cooperated with any government inquiry, and received government approval for the sued-upon conduct at the time they were reporting their inflated prices. In short, the "focus of the defense is not on what the Government knew; rather the defense focuses on whether the defendant acted knowingly, examining the effect of the Government's knowledge on the defendant." Michael J. Davidson, *The Government Knowledge Defense to the Civil False Claims Act: A Misnomer by Any Other Name Does Not Sound as Sweet*, 45 Idaho L. Rev. 41, 56 (2008) ("Interpreting the FCA to provide an absolute defense based on government knowledge of the specific falsity at issue, without a concomitant effect on the defendant's mental state, would lead to absurd

results."). Any evidence which first came to light during this litigation or at any time after the pertinent claims period, *a priori,* could not have impacted on defendants' scienter.

The sanction requested by Abbott highlights this central problem with defendants' spoliation motions. Abbott asks that the Court "shift to plaintiff the burden of negating 'government knowledge'." Dkt. 6097 at 23. This request demonstrates a fundamental misunderstanding regarding the potential significance of government knowledge. Spoliation of relevant evidence by the Government is not possible because the only relevant evidence is that which sheds light on what *defendants* knew and understood about whether the Government, with full understanding of defendants' use of mega-spreads, approved of that conduct.

The Court has already demonstrated its understanding of the relevancy dispute associated with the government approval defense. *See* Dkt. 5665 at 10-15. Accordingly, the Government will not re-brief the issue here beyond pointing out that acceptance of defendants' arguments regarding the legal relevance of such information would lead to a perverse outcome. The Government's efforts to investigate and obtain information about the abuse of a federal program should not provide a defense to those who are committing fraud. As a species of fraud or abuse becomes more extensive or creates a greater loss to the public fisc, the more likely it is to come under government scrutiny. Assigning some relevance to the Government's knowledge of suspected abuse in such a situation without examining it in the context of a defendant's scienter would lead to a counterproductive result. Inexplicably, *less* pernicious forms of fraud would be *more* susceptible to redress through an FCA case because they are more likely to have eluded detection and, therefore, not to have come to the Government's knowledge. Such a result would be a complete inversion of how Congress intended the FCA to work because the most flagrant abuse would present the greatest challenge to the Government's efforts to seek redress.

In prior decisions, the Court has described OIG's tireless pursuit of the "AWP issue" culminating in the issuance of the 2003 Compliance Guidance for Pharmaceutical Manufacturers. *In re Pharmaceutical Industry Average Wholesale Price Litig.*, 491 F. Supp. 2d at 41-44. It would be a travesty if, as a result of the OIG's dogged efforts to analyze, document, and publicize the waste of program funds associated with AWP abuse, the Department of Justice was disabled to any degree from seeking recovery from those who committed the abuse. Finally, the proposition that the Government's awareness that one of its programs may be the victim of fraud and its failure to dismantle or redesign a program somehow disables it from the civil prosecution of such fraud is completely without support in FCA jurisprudence.

B. Defendants Have Not Explained How Purportedly Spoliated Evidence Could Have Any Relevance in this Litigation

Defendants have not explained how any category or item of evidence noted in the spoliation briefs is relevant, much less "critical," under *any* legal theory. For example, Abbott asserts that the Government purportedly failed to preserve the workpapers "for several key OIG reports" and that the workpapers for reports that were produced "contain significant amounts of relevant information." Dkt. 6097 at 16. The Government has, in fact, produced workpapers for 58 OIG reports consisting of approximately 50,000 pages of material (exclusive of electronic data). During discovery, defendants extensively questioned seven OIG witnesses, who were collectively deposed for sixteen days. Notwithstanding this discovery, defendants still cannot identify the relevance of anything in the workpapers – they simply assert that the information is, in some undisclosed manner, "relevant." The truth is that the OIG workpapers are wholly irrelevant. The principle fact established by the thousands of pages of workpapers produced by the Government is that the audit and inspection work described in the publicly-issued reports

(which detail OIG's findings) was, in truth, performed by the OIG. This is hardly a revelation, nor is it dispositive of any issue in this case.

The single example of a document which Abbott suggests might have been found in a set of "missing" workpapers is strikingly un-compelling: "Abbott learned of an important 1987 *Lexington Herald* article which had been cited in [a] workpaper file, along with related evidence that has since been destroyed." Dkt. 6097 at 17. It is virtually certain in this case that a 1987 newspaper article would not amount to a relevant piece of evidence that would be entered against the United States at trial. Notably absent from Abbott's brief is any particularized explanation of how this example, or any of the others to which Abbott alludes, could conceivably be deemed relevant in light of the claims actually pled in these cases. The only potential relevancy of a newspaper article would be if a defendant could show that it somehow affected its scienter in reporting a false price – a factual issue that obviously will not be resolved by reference to OIG workpapers produced by the Government starting in 2007.

Markedly absent from any of the spoliation briefs is a claim by any defendant that it advised CMS about its AWP reporting and marketing practices and sought government approval for this conduct. That type of documentation would obviously be in defendants' own files. In fact, from discovery taken by the United States, it appears that there are no defense witnesses who will claim that any such exchange between CMS and defendants ever occurred.[9/] Moreover, virtually every Government witness deposed by defendants was asked whether he or she had any

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[9/] From 1991 to 2001, Abbott never: a) informed the federal Government of the contract prices it actually had in place with customers for the Subject Drugs; b) sought approval from the federal Government for its price reporting for the Subject Drugs; or, c) sought guidance from the United States concerning its price reporting conduct. Transcripts from the Rule 30(b)(6) Depositions of: Michael Sellers at 179:6-22; 180-183; 184:1-9; 310:3-21; (Ex. C-1) 487:2-22; 488:1-4; 491:14-22; 492:1-5 (Ex. C-2), David Fishman at 239:20-22; 240:1-7 (Ex. D-1), 643:2-9 (Ex. D-2).

communications with the individual defendants during the relevant claims periods. None testified that any defendant had sought, much less been given, approval to inflate AWPs. Accordingly, what defendants are essentially alleging is that the Government spoliated documents which communicated approval that was entirely unsolicited by defendants. There is simply no reason to believe that any such evidence ever existed.

Dey's brief adds nothing to the argument for spoliation. Indeed, the information set out in the Dey brief concerning the contents of the workpapers which the Government has produced militates against a finding of spoliation. Dey's brief lists documents contained in workpaper files associated with OIG's report relating to one of Dey's drugs, Albuterol Sulfate. Dkt. 6110 at 6. Dey then complains that one of the several OIG staff persons who worked on the report is no longer available to testify. Dey conveniently ignores the fact that OIG inspections and audits were never the work of a single individual and fails to mention that other OIG staff who worked on the report were deposed, some for multiple days. In any event, whatever point Dey is trying to make regarding the OIG's work on Albuterol Sulfate, it has little to do with document spoliation given the multiple citations to the contents of OIG workpaper files *which the Government produced.*

Finally, defendants ignore one of the most obvious points associated with the OIG's work analyzing drug pricing. There can be no plausible claim of spoliation with respect to the final reports themselves which describe the audit and inspection work, set out the findings, conclusions, and recommendations of the OIG, and also include the response of CMS, if any, to the OIG's recommendations. Even miscellaneous material from the workpapers, such as the *Lexington Herald* article noted above, was referenced in a final OIG report. The reports have been available on the OIG website for over a decade. In the event defendants want to continue to

flog some misguided argument about Government knowledge despite everything the Court has said and written on this topic, the final OIG reports themselves are surely sufficient.

C. Defendants are Not Entitled to a Finding of Spoliation with Respect to Claims Data

Abbott further claims that "key underlying payment data has been spoliated," and that "as Abbott will detail in its summary judgment papers, it is effectively impossible to calculate causation and damages with the underlying claims data and/or pricing arrays." Dkt. 6097 at 22. As indicated in the spoliation brief, Abbott's subsequent summary judgment motion also attacks the Government's damages estimate. *See* Dkt. 6186 at 10-21. Abbott's summary judgment memorandum, in turn, references a third brief, Abbott's motion to exclude the testimony of the Government's damages expert. *See* Dkt. 6177. Both Dey and Roxane have also taken up damages issues in briefs filed earlier this month and are seeking partial relief based on the extent of the data the Government used to estimate damages.[10/] A core issue in these briefs concerns whether the Government's expert has used sufficient data to support his damages estimate. As will be demonstrated in the next section of this brief, defendants' allegations regarding the Government's production of claims-related information are simply not true. As to the basis for the sufficiency of the data underlying the conclusions stated by the Government's damages expert, that issue will be addressed in the opposition to *Daubert* motions.

More to the point with respect to the damage calculation, however, is that while defendants argue that the Government's damages should have been calculated using more or different data (unavailing arguments which will be dealt with in the Government's oppositions to the above-noted motions), there can be no dispute that defendants have been given all the data

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[10/] *See* Dkts. 6178, 6200.

used by the Government's expert in reaching his conclusions. Abbott did ***not*** provide any of this claims data to its damages experts, except for one who was instructed by Abbott to refrain from performing any statistical analysis on the data.[11/] With respect to defendants' assertion that an alleged lack of state claims data undermines the reliability of the Government's damages estimates, that point can be explored during the cross examination of the Government's experts. Moreover, the purported insufficiency of the data is an issue about which defendants have indicated their experts will testify. Hence there is no potential for prejudice to defendants. To the extent they want to challenge the Government's damages estimate, any issue associated with the sufficiency of the data can be explored during the examination of the Government and defense experts. *See McGuire v. Acufex Microsurgical, Inc.*, 175 F.R.D. at 156 (finding spoliation sanction inappropriate even where party destroyed discoverable information and noting that matter could be explored on cross examination at trial).

In this situation, any challenge to the expert's conclusions is not properly framed as a spoliation issue. As for Abbott's request that, as a spoliation sanction, the Court should "eliminate damages for all Medicaid claims where the Government's damages calculation does not use detailed claims data (from the state) for that particular claim," (Dkt. 6097 at 22) notably lacking from Abbott's brief is any legal support for this sanction *in a spoliation context*. This deficiency is not surprising given that challenges to damage estimates, and challenges to whether an estimate is sufficiently supported by underlying data are typically resolved either in the context of *Daubert* challenges or during the expert cross-examination.

[11/] *See* Dep. Transcripts of Abbott Damages Experts, Steven J. Young at 563-570 (Ex. E) and James W. Hughes at 280-287 (Ex. F).

Courts generally decline to consider whether there has been a loss of data relating to alleged damages in the context of a spoliation motion. *See, e.g., Loveless v. John's Ford, Inc.*, 232 F. App'x. 229, 236 (4th Cir. 2007) (concluding that failure to preserve evidence used to calculate damages did not warrant sanction for spoliation when opposing party was capable of calculating damages); *Lampi Corp. v. American Power Prods. Inc.*, No. 93 C 1225, 2004 WL 1656547, at *2 (N.D. Ill. July 22, 2004) (denying an adverse inference in the calculation of damages for alleged destruction of relevant sales records and summaries when sales for the relevant damage period could be calculated with other produced evidence). Even in a case where a party intentionally destroyed "the only yardstick to measure accurately defendant's guilt in dollars" and a district court imposed personal sanctions on one party's legal counsel based on their handling of the litigation, the court ultimately looked to available evidence to estimate damages rather than engaging in wholesale presumptions. *Beatrice Foods Co. v. New Eng. Printing & Lithographing Co.*, 889 F.2d 1171, 1175 (Fed. Cir. 1990).

Abbott argues that sanctions for spoliation should be imposed in this case based on its speculation that purportedly destroyed evidence may have been "the smoking gun." Dkt. 6097 at 10 (citing *Miller v. Holzmann*, No. 95-01231, 2007 WL 172327, at *5 (D.D.C. Jan. 17, 2007)). Claims data will not be a "smoking gun" with respect to the damages alleged by the Government and there is no possibility that it will be exculpatory. The Government's damages estimates will only be considered by a jury after it has determined liability. *Chereskin v. United States,* No. 06-C-1269, 2009 WL 1507688, at *4 (E.D. Wis. May 29, 2009) (denying a motion to sanction the Government for alleged spoliation where the "government has offered good faith - even mundane- explanations for the alleged discrepancies in these records, and the details of these are not worth relating except to say that there are no smoking guns here.").

II. THE GOVERNMENT HAS NOT SPOLIATED ANY EVIDENCE, RELEVANT OR OTHERWISE

The record largely ignored by defendants demonstrates: (A) there has been an abundance of information in the public domain reflecting the Government's knowledge relative to the subject matter which defendants have asserted is critical to the Court's understanding of the drug benefit at issue; (B) the Government took reasonable and timely steps to preserve evidence; (C) the Government has produced hundreds of thousands of pages of documents and millions of lines of data in this MDL; (D) there is no evidence that spoliation occurred; and (E) defendants' spoliation allegations regarding particular documents are not true.

A. There Has Long Been an Abundance of Government Information Regarding Drug Payment Policies in the Public Domain

At the outset of the lawsuit brought by the United States, Abbott asserted that "the Government has known for nearly 40 years that the compendia's published prices exceed by a substantial margin the product's actual acquisition cost." In support of this assertion, Abbott submitted an appendix "which provide[d] and summarize[d] four decades worth of public documents showing the Government knew compendia prices were not acquisition costs." Abbott's assertions about the state of the public record have been echoed by Dey and Roxane. *See* 3508-1 at 10-11; Dkt. 6197 at 11. In light of the abundance of information regarding what the Government learned about compendia AWPs over the years, in order to accept defendants' spoliation allegations, one would need to believe that government agencies spoliated evidence with surgical precision – that is, the Government lost only those documents which would support a defense in this litigation. There is no basis in the record of this case or in logic for such a conclusion.

In previous decisions, the Court described the work done by OIG to assess the extent to which AWPs reported in the compendia reflected market place prices and cited to specific reports *published by the Government* which document the "excessive pricing" for specific drugs. As noted by the Court, OIG "has found evidence that over the past several years Medicare has paid significantly more for drugs and biologicals than physicians and pharmacists pay to acquire such pharmaceuticals." *In re Pharm. Indus. Average Wholesale Price Litig*., 491 F. Supp. 2d at 42. In light of the Court's findings on this point and the extensiveness of the OIG's work in this area, there is simply no discovery issue here, much less a valid spoliation claim. The Government's efforts to understand the drug marketplace and the prices actually available to purchasers has been an entirely transparent exercise, the progress of which is reflected in the publicly-issued OIG reports.

All that being said, arguably the greatest flaw with defendants' spoliation arguments is their failure to take into account the most fundamental feature of Government policy-making, which is, that it is done on the public record. According to Abbott, the "Government has produced remarkably few contemporaneous substantive discussions on AWP-related matters." Dkt. 6097 at 11. This statement is untrue on multiple levels. First, substantive discussions between OIG and CMS are reflected in the recommendations stated in OIG's reports and CMS's written responses to the OIG recommendations, which are appended to the reports. Second, defendants can look to the substantive explanations of CMS, as well as the agency's responses to public comments about notices of proposed rulemakings, which are published in the Federal Register – and, of course, to the controlling regulations, statutes, and official legislative histories. This is precisely what Judge Saris did when she ruled on the legal definition of the term AWP in November 2006. *See In re Pharm. Indus. Average Wholesale Price Litig*., 460 F. Supp. 2d at

279-287. Third, the Government agreed to make available for inspection and copying CMS's Official Rulemaking Records for regulations designated by defendants. With the exception of one regulation, defendants passed on that opportunity. Fourth, as explained in a later section of this brief, the Government has produced, logged as privileged, or submitted *in camera,* documents containing the substantive discussions which defendants assert are missing.

Defendants' relentless pursuit of some hypothetical scrap of paper that purportedly existed in the corner of some unspecified government office and which would somehow reveal a secret, non-public, purpose behind the Government's use of AWP as a payment benchmark ultimately evidences a level of desperation on their part. What is missing at this juncture is not some document that has been spoliated. Rather, it is clear that defendants have no evidence to support a scienter defense. They cannot show that they believed that it was appropriate to report inflated prices based on the Government's full understanding and purported approval of such conduct. The reason there is a lack of evidence to support this defense is not because it was spoliated – it simply never existed.

B. Defendants' Allegations Concerning a Lack of Preservation Are Not True

1. The Government Took Reasonable Steps to Preserve Evidence

The instant spoliation motion is the second time that Abbott has challenged the steps taken by the Government to preserve evidence. Abbott's prior unsuccessful motion for a preservation order, filed in September 2007 (Dkt. 4711), brought allegations which have now been repeated in the spoliation brief. Both the prior and current brief incorrectly assert that the Government's preservation efforts have been limited to the circulation of a single preservation memorandum in January 2007. In response to Abbott's prior motion, the Government both

summarized information disclosed during the depositions of eight Government employees who had testified about the Government's preservation and production of documents and data and submitted copies of documentation regarding the preservation efforts implemented by the Government. *See* Dkt. 4808.

As explained to Abbott over the course of eight depositions and further laid out in a brief filed approximately 18 months ago, the Government began preserving documents well before January 2007. Contrary to defendants' assertions, the documentation produced in this litigation shows that, pursuant to a 1992 preservation instruction, CMS and its contractors have preserved claims records dating back to 1986. Dkt. 4808, Ex. A at 24-34; Ex. B at 8-10. Moreover, Abbott learned in discovery that CMS has long had in place record retention policies which provide that large portions of the agency's records are maintained in perpetuity. *Id*. Ex. C at 55-56, 62-65, 83-89. CMS's record retention policies directed employees to preserve hard-copies of any electronic document, including emails, that would constitute an agency record. *Id.* Ex. A at 102-105, Ex. D at 57,67. The record from the October 2007 briefing also reflects that, after CMS contractors received third party subpoenas in both the Lupron and AWP MDLs in 2003, CMS issued broad preservation instructions to its Medicare contractors. *Id* Ex. A 68-71; Ex. B at 1-4. When CMS received additional MDL subpoenas in early 2004, CMS issued agency-wide preservation instructions. *Id*. Ex. A at 71-74; Ex. B at 5-7.

After the United States intervened in these consolidated cases, defendants collectively served in excess of 250 document requests (not counting subparts within individual requests). Despite the massive over-breadth and irrelevance of defendants' discovery requests, in January 2007, CMS took additional steps to insure that any material responsive to those requests was preserved and produced by its staff. *See id*., Ex. A at 77-85; Ex. C at 50-51, 62; Ex. E at 161-62.

Notwithstanding the particular steps taken by the Government to issue preservation instructions relating to the AWP litigation, the essential point which defendants ignore is that the documents which they contend are a "critical" source of evidence in this case are in agency files which are permanently preserved, regarless of any litigation hold directive. For example, with respect to the regulations specifying Medicare's methodology for determining the payment amount for drugs, CMS maintains both an Official Rulemaking Record and a Rulemaking Support File. Indeed, the parties have engaged in extensive litigation over privilege and relevancy issues associated with the Rulemaking Support Files, Abbott having filed multiple briefs relating to this source of material. *See, e.g.,* Dkts. 4791, 5676, 5813. An important initial point with respect to these files is that, based on testimony and declarations by CMS personnel and from documents produced or made available for inspection by the Government, defendants have a clear understanding (a) regarding the type of material in these files and most significantly with regard to the spoliation motions, (b) that these files are not subject to any destruction schedule and still exist. *See, e.g.,* Dkt. 4791 at 3 (Abbott's motion to compel production of, *inter alia*, Rulemaking Support Files). In short, with respect to the CMS files which have been the subject of the most focused interest by defendants, the repeated motions practice relating to this material is expressly premised on defendants' understanding that the files have been permanently preserved pursuant to CMS's document retention policies, contrary to the representations in defendants' briefs.

2. The Government Took Timely Steps to Preserve Evidence

Abbott attempts to make much of the fact that the CMS preservation memorandum which explicitly references the *qui tam* case against Abbott was issued in January 2007, while ignoring the 2003 and 2004 preservation directives which were issued in reference to the broader

MDL litigation. Here, Abbott is arguing form over substance. Given the virtually complete overlap between the particular subject matter of this MDL and the claims in the intervened *qui tam* cases, there is no reason for the Court to find that preservation directions issued prior to January 2007 somehow were inapplicable to the subject matter of the Government's cases against Abbott and Dey.

Defendants argue that the Government's obligation to take steps to preserve evidence arose at the time the *qui tams* were filed under seal and served on the Department of Justice - 1995, in the case of Abbott and 1997 in the case of Dey. Using the filing date of a *qui tam* to trigger a preservation obligation is not supported by the case law nor called for under the facts and circumstances of this case. A duty to preserve evidence begins when litigation is pending or reasonably foreseeable. *West v. Goodyear Tire & Rubber Co.*, 167 F.3d 776, 779 (2nd Cir. 1999); *Silvestri v. General Motors Corp.*, 271 F.3d 583, 591 (4th Cir. 2001).

The complaint filed by Ven-A-Care in 1995 named over 50 drug companies - a significant sector of the pharmaceutical industry. The allegations covered hundreds of drugs and broad allegations of misconduct spanning over a decade. After years of investigation and discussion with dozens of the defendants, the United States ultimately began litigation with only three defendants in 2006. Implementing a litigation hold when the *qui tam* was first filed would have proven unnecessary and created a needless and costly burden for the affected agencies.

From 1995 to 2008, approximately 3,000 *qui tam* suits were filed involving fraud against HHS. (Approximately another 2,000 *qui tam* suits were filed during this period alleging fraud against other government agencies, such as the Departments of Defense and Transportation, and others.) CIVIL DIV., U.S. DEP'T OF JUSTICE, FRAUD STATISTICS OVERVIEW (2008), http://www.usdoj.gov/opa/pr/2008/November/fraud-statistics1986-2008.htm. Over roughly the

last twenty years, the United States has intervened in approximately twenty two percent (22%) of the cases that were filed, Government-wide, during that period. In many of the intervened cases, intervention was contemporaneous with dismissal of the *qui tam* action in order to complete settlement with the defendant and litigation did not commence. In those cases where the Government declined intervention, the relators frequently did not proceed with litigation, choosing to dismiss cases voluntarily, or settle before litigation occurred. Thus, the filing of a *qui tam* action does not necessarily result in litigation against the named defendants. In fact, a small percentage of the filed *qui tam* caseload overall results in actual litigation.

Courts have recognized that the duty to preserve evidence does not extend to the point where it becomes an unreasonable burden or cover every conceivable document. *Zubulake v. UBS Warburg LLC,* 220 F.R.D. 212, 216-17 (S.D.N.Y. 2003) ("Must a corporation, upon recognizing the threat of litigation, preserve every shred of paper, every e-mail or electronic document, and every backup tape? The answer is clearly, 'no'. Such a rule would cripple large corporations, like [defendant], that are almost always involved in litigation."); *Concord Boat Corp. v. Brunswick Corp.,* No. LR-C-95-781, 1997 WL 33352759, at *4 (E.D. Ark. Aug. 29, 1997) ("[T]he threat of litigation is ever present for large, successful corporations. Arguably, most e-mails, excluding purely personal communications, could fall under the umbrella of 'relevant to potential future litigation.'. . . Thus, it would be necessary for a corporation to basically maintain all of its e-mail. Such a proposition is not justified. . . . The long-term storage expenses would be staggering.") Similarly, the possibility of *qui tam* suits being filed is ever present for the United States and document preservation is just as expensive for the Government as it is for private entities - likely considerably more so given the broad scope of the Government's programs.

In any event, determination of the precise date on which a preservation obligation arose with respect to the claims in this case is not critical given (a) CMS's policies with respect to permanent preservation of documents, (b) the more particularized directives issued by CMS in the early and mid-1990s, and (c) defendants' failure to describe any relevant evidence, or even a category of relevant evidence, that has actually been spoliated.

C. The Government Has Produced Hundreds of Thousands of Pages of Documents and Correspondence and Millions of Lines of Data

The effectiveness of both the agency's general retention policies and the particular preservation instructions by CMS are apparent given the substantial volume of material (hard copy and electronic) produced by the Government during this litigation. The result has been the production of over 600,000 pages of material and hundreds of millions of lines of data. As noted above, the Government has produced tens of thousands of pages of workpapers relating to OIG reports. Defendants' claim that the Government failed to retain "contemporaneous, substantive, discussions on AWP related matters" is belied by the record. Defendants have extensively used documents produced by the United States at deposition. During the discovery phase of this case, defendants interrogated 94 individuals employed, or formerly employed, by federal and state governments or their contractors over the collective span of more than 140 full deposition days. During the depositions, defendants marked and used *in excess of fourteen hundred exhibits*. The vast bulk of the those exhibits were documents that originated with federal or state agencies. Approximately half the exhibits used were documents created in the 1990s - *i.e.* the claims period at issue in, for example, the Abbott case.

The more than 600,000 pages of material that was imaged, bates-numbered, and produced by the Government does ***not*** include files made available in their original state to defendants for

inspection and copying. As noted above, Medicare payment methodology is a creature of regulation. At the outset of these cases, Abbott requested production of the Official Rulemaking Record for all regulations relating to Medicare and Medicaid payments for drugs. Abbott requested the Government give priority to producing files relating to nine specified regulations or proposed regulations. In January 2007, the Government responded to Abbott's request and advised that it had identified 105 boxes of material comprising the Official Rulemaking Record for CMS's 1991 regulation concerning Medicare payments for prescription drugs. At that time, the Government further offered to make files relating to the other regulations available for inspection and copying at CMS headquarters – based on the agency's need to retain custody of the original documents in the Rulemaking Record. The Government asked Abbott to prioritize the other eight regulations on its list so that the rulemaking files could be made available on a phased basis, which was the only way to handle the volume of material involved.

In mid-2007, attorneys for Dey and Roxane appeared at CMS to review the 1991 files noted above. These were the only Rulemaking Records reviewed by defendants. They never scheduled any review of records for the other eight regulations as to which Abbott had requested priority production. With respect to Abbott's assertion that "critical" documents relating to drug payment policy have been lost, given that Abbott's attorneys never scheduled any review of the rulemaking files which have indisputably been preserved and which the Government agreed to make available, the obvious question is, how do they purport to know this? In any event, in light of this record, there can be no colorable spoliation claim regarding agency Rulemaking Records.

The sheer volume of the production by the United States in this litigation makes it difficult to effectively convey the nature and breadth of the material that has been produced and the extent to which it contains information about substantive issues. The parties' litigation over

discovery from discrete sources of Government documents, however, presents a window on the Government's production and demonstrates that CMS preserved documents relating to substantive issues which defendants claim have been spoliated. As noted above, in addition to the Official Rulemaking Record, CMS maintains a separate Rulemaking Support File which has been the subject of motions in this case. In October 2007, Abbott moved to compel production of material from the Rulemaking Support Files as well as CMS's Office of Legislation. The Magistrate Judge denied Abbott's motion. In response to Abbott's objections, Judge Saris slightly modified the Magistrate's Order and directed that the Government review the files of the Office of Legislation and the Rulemaking Support Files "for documents relating to Abbott's marketing the spread or the drugs at issue in this litigation." Docket Order of Mar. 14, 2008. During subsequent oral hearings, Judge Saris marginally expanded the scope of material that the Government should produce or submit *in camera* to include documents which relate to mega-spreads for inhalants and infusion drugs, Vancomycin, and the issue of cross-subsidization. The Government's September 2008 *in camera* submission to the Court contained precisely the types of documents which defendants allege were spoliated. For example, the Government submitted memoranda setting out internal agency comments on 1991 draft rules (from the Rulemaking Support Files) and draft internal CMS memoranda addressing the issue of whether Medicare carriers could use information obtained by the Department of Justice as an alternate source of AWPs when setting drug payment levels (from the Office of Legislation). Indeed, the Court ordered the release of some of this material to defendants. Dkt. 5665 at 16-20. The material in question reflects the types of contemporaneous discussions that Abbott inexplicably, and without any real basis, claims has been spoliated. In light of the complete record in this case and the

documents that have been produced or made available for inspection, there is no legitimate basis to assume that any spoliation of evidence pertinent to any substantive issue has occurred.

Abbott's allegation that electronically stored information has been spoliated is also not in accordance with the Government's production. As noted above, CMS employees operate under a standing policy that requires that they print hard copies of electronic information that may constitute agency records. Documents produced by the Government evidence compliance with this directive. The Government production included in excess of 8,500 e-mails produced as hard copy records - several thousand of those were created in the early to mid-1990s. Material covered by the Governments' privilege logs includes another 934 e-mails. Defendants used over 70 e-mails during the depositions of Government witnesses. Among the 135 or more documents submitted *in camera* to either the Court or Special Master, were 15 hard copy versions of e-mails. In light of the entire record in this case, there is no reason to conclude that the Government's retention policies with respect to information on computer hard drives allowed for the spoliation of documents relevant to claims or defenses in this case.

As for claims data, as previously noted, defendants' allegations do not properly implicate a spoliation sanction. Nor are Abbott's assertions even true. Abbott pursues a finding of spoliation of state claims data without demonstrating that any state claims data has actually been spoliated and instead relies on innuendo regarding "gaps in the evidence." Abbott alleges that the Government's damages are derived from claims data from only ten states. These assertions are misleading in light of the information defendants have omitted. For example, Abbott fails to note that the United States has produced to defendants data regarding every NDC (National Drug Code) for every state for every time period for which any damages are sought in these cases (and

has refrained from asserting damages for any time frame for which there is no data). For many time periods, the United States has even produced redundant data from different databases.

As part of their participation in Medicaid, each state regularly transmits its drug utilization data to CMS every year. That utilization data has not only been preserved, but has been produced to the defendants. The data submitted by the states to CMS is of two types. The first was initially known as the State Medicaid Research Files ("SMRF") and most recently as the Medicaid Analytic Extract ("MAX"). These two sets of data are in similar formats and are generally referred to together as "SMRF/MAX. The SMRF/MAX data is claims level data which includes various data elements including, for example, the NDC, date of service, charged amount, paid amount, quantity, and date of payment. The second category of data collected directly from the states by CMS is known as State Drug Utilization Data ("SDUD"). This data provides detailed information about drugs dispensed by pharmacies and reimbursed on an NDC basis by the Medicaid programs of each state, including the total number of prescriptions filled and the total amount paid for each NDC in every quarter. This information on NDC-state-quarter-specific Medicaid spending and utilization for the 1991 through 2007 time period is publicly-available on the CMS website. A detailed description of the scope of the SDUD data as well as that of the SMRF/MAX data was included with an initial report of the Government's damages given to defendants in June 2008.

In addition to the SDUD/SMRF/MAX data, both the United States and Abbott have approached many states directly to obtain claims data. The Government has given defendants all of the relevant claims data it procured from the states.[12/] In total, Abbott is in possession of

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[12/] The United States obtained this data directly from approximately 27 states and provided it to the defendants in the course of discovery. In two years of fact discovery, including the extra nine months allowed by the Court for the express purpose of securing additional data from the states,

detailed claims level data procured from a total of thirty states for at least part of the time period at issue, which for Abbott runs through 2001 (representing approximately 236 years of data). In connection with Dey's drugs, data has been procured for at least part of the time period at issue from thirty-three states (representing over 357 years of claims data). In sum, the United States has produced data from every state (and the District of Columbia) in the form of SDUD/SMRF/MAX data, and from at least thirty states (or more) in the form of detailed claims data obtained directly from the states. Abbott's suggestion that data has only been secured from ten states is simply not true.

Abbott has failed to support its allegations regarding the spoliation of Medicare pricing arrays and state MAC (Maximum Allowable Cost) information with any evidence. As to the arrays, Abbott's argument is limited to a brief description of an "array," and a conclusory statement that "many carriers' arrays are now lost." Dkt. 6097 at 14-15. Abbott has not provided any evidence that any Medicare arrays are even missing, much less any explanation as to why that could even be the case. Indeed, from the depositions of carrier personnel taken by Abbott, it appears, not that documents were destroyed, but rather that documents with price arrays had been retained and were in off-site storage, but were not retrieved because to do so would have been unduly burdensome.

As for the state MAC information, Abbott's motion provides even less support, given that it has failed to identify what evidence was purportedly spoliated, much less explain what facts the spoliation claims are based upon. In any event, as noted above, any issue regarding carrier arrays is more appropriately considered in the context of challenges to the conclusions stated by the Government's experts, not via a spoliation motion.

Abbott collected data directly from approximately three states.

D. There is No Evidence that Any Spoliation Actually Occurred

Abbott's contention that States have spoliated documents relies, virtually to an exclusive degree, on a 2006 e-mail from a New York pharmacy official who expresses frustration with the burdens attendant to AWP litigation. Notably absent from defendants' briefs is any description of the material the states have produced in response just to the subpoenas served in these FCA cases, to say nothing of material produced by states in other cases that are part of the MDL or in the state actions currently or formerly pending around the country. The United States estimates that states have produced in excess of 1.7 million pages of material in response just to the third-party subpoenas in the Government's FCA cases.

With respect to the 2006 e-mail from a state official, Abbott reads far more into the document than can be reasonably inferred from the message when its entire text is considered. Abbott asks the Court to find that the e-mail is somehow evidence of "more than a decade of document destruction" by state Medicaid agencies. There is no basis in the e-mail quoted by Abbott to infer that states generally, or the State of New York specifically, set out a deliberate program of document destruction. If New York officials had actually set out to spoliate documents which arguably could be construed as damaging to their case, presumably the first document that would have been destroyed is the one appended to Abbott's brief. Plainly, the e-mail was not only preserved but obtained by Abbott's counsel in connection with this or other litigation (given the lack of a Bates number, the source of the document is unclear). In light of its obvious preservation, the e-mail is more appropriately seen as a benign expression of one individual's frustration - which, if one considers the contentiousness in these cases, is understandable. Indeed, the sentiments expressed in the e-mail may well be reflective of what

most non-litigators feel as the demands of discovery in a large-scale litigation disrupt the performance of their normal duties.

Moreover, if one were to give credence to Abbott's contention that states have engaged in "more than a decade of document destruction," it would be difficult to understand what some New York official had to complain about with regard to record retention in 2006 – which is when the e-mail was drafted. There is nothing in the e-mail stating that state Medicaid materials have been spoliated. In fact, from the part of the email which was not quoted in Abbott's brief, the plain implication is to the contrary. The author states that he "had many meetings with AG and Department of Health lawyers and . . . had to provide many boxes of documentation about what [the state] knew about AWP over many years." A single e-mail expressing frustration with the burdens of preservation and discovery in a mammoth multi-party case is far too slender a reed upon which to infer extensive multi-state spoliation of relevant evidence. This is especially so when the more reasonable inference to be drawn from the tone and content of the email, considered with the message to which it responded (also a part of Abbott's Ex. A), is that state personnel have taken their search and production obligations in AWP litigation seriously and have acutely felt the burden of those responsibilities.

In light of that single e-mail, Abbott's motion lacks sufficient evidence upon which the Court can find spoliation of evidence by the states.

E. Defendants' Spoliation Allegations Regarding Particular Documents Are Unsupported

Although Abbott's spoliation brief for the most part sets out sweeping assertions of purported spoliation, it also contains one or two more particularized allegations. These allegations regarding particular documents fail to withstand scrutiny. With respect to spoliation

of documents by the OIG, defendants assert that "even when some [OIG] workpapers still exist, important documents have often been lost. For example, the Government has been unable to locate key documents relating to its two rounds of 'AWP audits' during the 1990s" including electronic spreadsheets and the minutes of exit conferences with CMS. Dkt. 6097 at 17. Abbott's allegations regarding spoliation of OIG work papers associated with the 1994 and 1997 AWP audits are fiction.

With respect to the electronic spreadsheet noted above, it has not been spoliated. It was produced by the United States. *See* Ex. G. As for the purported exit conference minutes of meetings between CMS and OIG regarding these two audits, it appears there were no exit conferences with CMS for these two audits. The reports at issue involved OIG audits of state programs and were intended to develop information for the states. Complete workpaper files relating to these audits were preserved and produced to defendants. Included in those workpapers are "records of discussion" which document meetings attended by personnel from OIG and CMS (which at that time was called HCFA) as well as State Medicaid Pharmacy Representatives. *See* Ex. H. The OIG auditor with principle responsibility for conducting the audits and maintaining the workpapers was not able to recall any meeting with CMS regarding these audits other than the ones referenced in the records of discussion noted above. In sum, based on the scope and purpose of the audits, the fact that full workpaper sets – which include records of discussion for meetings attended by OIG, CMS, and state personnel – were preserved, and the lack of any evidence suggesting that separate "exit conferences" were held between OIG and CMS, the most reasonable conclusion one can reach os that there were no additional conferences. Hence there were no meeting records to preserve – other than the ones produced to defendants. In any event, after the Special Master completed a particularized review of dozens of

documents in this category that had been submitted *in camera*, he found that this type of material was not even discoverable.

Defendants' current spoliation motions are an old litigation ploy: when one party cannot produce the evidence needed to support a defense, blame the other side for having lost or hidden it. Indeed, the motions are tantamount to an admission that inferring Government approval from the current record is unsupportable. Hence, the need to argue that the non-existent evidence was lost - any concession that it simply does not exist would be critically damaging to defendants' case.

III. CONCLUSION

Based on the foregoing, defendants' motions for a finding of spoliation and sanctions should be denied.

Respectfully submitted,

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Dated: July 20, 2009

I hereby certify that I have this day caused an electronic copy of the above **MEMORANDUM IN OPPOSITION TO DEFENDANTS' MOTIONS FOR A FINDING OF SPOLIATION AND FOR SANCTIONS** to be served on all counsel of record via electronic service pursuant to Paragraph 11 of Case Management Order No. 2 by sending a copy to LexisNexis File & Serve for posting and notification to all parties.

/s/ Justin Draycott

Dated: July 20, 2009 Justin Draycott